MAR 1 9 2001

Section 7 - 510(k) Summary of Safety and Effectiveness

7.1 Statement	This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92
7.2 Submitter	Endius, Inc. 23 West Bacon Street Plainville, MA. 02762
7.3 Company Contact	Susan Finneran QA/ RA Manager 508-643-0983 ext. 114
7.4 Device Name	**Proprietary Name:** TriFix Spinal Fixation System **Common Name:** Pedicle Screw System , Non-pedicle spinal fixation system **Classification Name:** Spinal Pedicle Screw (MNI),Spinal Interlaminal fixation orthosis (KWP), Spondylolithesis Spinal Fixation Device System (MNH)
7.5 Predicate Legally Marketed Devices	TriFix Spinal System cleared via premarket notification K992147 for Advanced Spine Technology, Inc.

7.6 Device Description	The Advanced Spine Technology TriFix Spinal System is a system that is intended to be used for posterior lumbar fusion procedures. The system is manufactured from titanium which complies with ASTM F136. The components, which are included as part of the system, include screws, rods, plates, and accessory connection components.
7.7 Device Indications and Intended use	The TriFix Spinal System is a pedicle screw system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis). The posterior TriFix Spinal System is also indicated for pedicle screw fixation for severe spondylolithesis (grades 3 and 4) at L5-S1, in skeletally mature patients, when autogenous bone graft is used, when affixed to the posterior lumbosacral spine, and intended to be removed after solid fusion is attained. Levels of fixation are from L3-S1. The posterior TriFix System, when not used with pedicle screws is indicated for hook, wire, and /or sacral screw fixation from T1 to the ilium sacrum. The non-pedicle screw indications are spondylolithesis, degenerative disc disease, (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), deformities (scoliosis, lordosis and kyphosis), tumor, fracture, and previous failed fusion surgery.
7.8 Substantial Equivalence	The new components (components with the new torque tightening specification of the TriFix System are substantially equivalent to the components of the TriFix System which were previously cleared by the premarket notification process via K992147. Testing was also completed as per ASTM F1717 in order to demonstrate equivalence.

7.9 Table of Substantial Equivalence

Device Name	TriFix Spinal System (Cleared)	Component where torque value has been changed
Product Components	As per K992147, K000766, or K001627.	Identical
Indications for Use	See above	Identical
Materials	Stainless Steel or Titanium	Stainless Steel or Titanium
Product Labeling	Instructions for use and box labeling including all of the necessary warning statements	Instructions for use and box labeling including all of the necessary warning statements
Packaging/ Sterilization	Non-sterile, single use only	Non-sterile, single use only

Applicant _____ Date 2/21/01

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 9 2001

Ms. Susan Finneran
Director of Regulatory Affairs
Endius, Inc.
23 West Bacon Street
Plainville, Massachusetts 02762

Re: K010535
Trade Name: Tri-Fix Spinal System
Regulatory Class: Class II
Product Code: MNH, MNI, KWP
Dated: February 22, 2001
Received: February 23, 2001

Dear Ms. Finneran:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Milhorn

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K010535

Device Name: TriFix Spinal Fixation System (Stainless Steel and Titanium)

Indications for Use:
The TriFix Spinal System is a pedicle screw system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis).

The posterior TriFix Spinal System is also indicated for pedicle screw fixation for severe spondylolithesis (grades 3 and 4) at L5-S1, in skeletally mature patients, when autogenous bone graft is used, when affixed to the posterior lumbosacral spine, and intended to be removed after solid fusion is attained. Levels of fixation are from L3-S1.

The posterior TriFix System, when not used with pedicle screws is indicated for hook, wire, and /or sacral screw fixation from T1 to the ilium sacrum. The non-pedicle screw indications are spondylolithesis, degenerative disc disease, (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), deformities (scoliosis, lordosis and kyphosis), tumor, fracture, and previous failed fusion surgery.

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Concurence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

(Posted July 1, 1998)

for Mark N Milhern

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010535